

K080074

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Name: ACE Surgical Supply Co., Inc.
Submitter Address: 1034 Pearl St., Brockton, MA 02301
Contact Person: J. Edward Carchidi, DDS
Phone Number: (508) 588-3100
Fax Number: (508) 523-3140
Date Prepared: January, 2008
Device Trade Name: ACE Tru-FIX™ Implant System
Device Common Name: Endosseous Implant Screw
Classification Name: Implant, Endosseous, Root form, product code DZE
Predicate device: ACE Surgical Miniboneplate system, K951392
ACE Surgical Orthodontic Bone Screw System, K061397
Reason for submission: Not previously marketed in the USA

FEB 14 2008

Device Description and Materials:

The ACE Tru-FIX™ Implant System is a set of machined surgical grade titanium alloy (Ti-6Al-4V ELI) screws, intended to stabilize and support bone graft and or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects. The implants are supplied sterile in 3.0 mm head diameter, and in lengths of 4.5, 6, 7.5, 9.0, 10.5, 12.0, 13.5, and 15 mm, in standard tray packaging and include placement instruments.

The screw raw material is Ti-6-AL-4V ELI per ASTM F136 standard. The candidate devices are identical in materials and characteristics to that cleared under K951392. These screws are supplied sterile in standard Tyvek™ trays.

The ACE Surgical TRU-Fix™ Implant System is a comprehensive system retaining prosthetic components, auxiliary components, and surgical tools as does the predicate ACE Surgical Miniboneplate system.

Intended Use:

The ACE Tru-FIX™ Implant System is indicated for use to stabilize and support bone graft and or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects

Substantial Equivalence/ Device - Technological Characteristics and Comparison to Predicate Device(s):

The ACE Surgical TRU-Fix™ Implant System is substantially equivalent to the ACE Surgical Orthodontic Bone Screw System, K061397 and ACE Surgical Screw Miniboneplate System, K951392

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the ACE Surgical TRU-Fix™ Implant System to the specified predicate devices are: 1) device description, 2) indications for use, 3) bench test results, 4) materials, and 5) labeling. In particular, the bench testing demonstrated there was no difference in the performance, safety, or effectiveness between the ACE Surgical TRU-Fix™ Implant System and the specified predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 14 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

J. Edward Carchidi, DDS
President
ACE Surgical Supply Company, Incorporated
1034 Pearl Street
Brockton, Massachusetts 02301

Re: K080074
Trade/Device Name: ACE Tru-FIX™ Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 11, 2008
Received: February 12, 2008

Dear Dr. Carchidi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

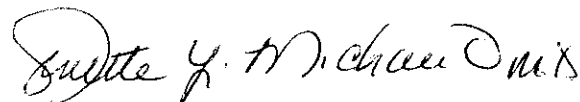
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: ACE Tru-FIX™ Implant System

Indications For Use:

The ACE Tru-FIX™ Implant System is indicated for use to stabilize and support bone graft and or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial bone defects

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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